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DATE: Thursday, June 30, 2005

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<i>DB=USPT; THES=ASSIGNEE; PLUR=YES; OP=ADJ</i>			
<input type="checkbox"/>	L10	L9 and 3rd adj generation	1
<input type="checkbox"/>	L9	L8 and ELISA	555
<input type="checkbox"/>	L8	kit and HCV	1058
<input checked="" type="checkbox"/>	L7	L3	36
<i>DB=USPT,USOC,EPAB,JPAB,DWPI; THES=ASSIGNEE; PLUR=YES; OP=ADJ</i>			
<input type="checkbox"/>	L6	L4	0
<i>DB=USPT; THES=ASSIGNEE; PLUR=YES; OP=ADJ</i>			
<input type="checkbox"/>	L5	L3 and 3rd adj generatioon	0
<input type="checkbox"/>	L4	L3 and third adj generation	0
<i>DB=PGPB,USPT,EPAB,JPAB,DWPI; THES=ASSIGNEE; PLUR=YES; OP=ADJ</i>			
<input checked="" type="checkbox"/>	L3	HCV adj ELISA	48
<input checked="" type="checkbox"/>	L2	HCV diagnostic reagent	2
<input type="checkbox"/>	L1	3rd adj generation and HCV diagnosis	0

END OF SEARCH HISTORY

1887 ABBOTT
2 ABBOTTS
1888 ABBOTT
(ABBOTT OR ABBOTTS)
24869 DIAGNOSTICS
L13 42 ABBOTT (W) DIAGNOSTICS

=> L9 and HCV
9298 HCV
17 HCVS
9302 HCV
(HCV OR HCVS)
L14 0 L9 AND HCV

=> ELISA
57755 ELISA
2201 ELISAS
L15 58681 ELISA
(ELISA OR ELISAS)

=> L9 (1) L15
L16 1 L9 (L) L15

=> D L16 IBIB ABS

L16 ANSWER 1 OF 1 CAPLUS COPYRIGHT 2005 ACS on STN
ACCESSION NUMBER: 2000:857936 CAPLUS
DOCUMENT NUMBER: 135:59836
TITLE: Development of one-step enzyme linked immunosorbent assay for hepatitis b surface antigen utilizing monoclonal antibodies
AUTHOR(S): Buddhirakkul, Nongluk; Buddhirakkul, Prayute; Balachandra, Kruavon; Jongtrakulsiri, Suttichoke
CORPORATE SOURCE: Department of Medical Sciences, National Institute of Health, USA
SOURCE: Thai Journal of Health Research (2000), 14(1), 19-26
CODEN: WWWKAS; ISSN: 0857-4421
PUBLISHER: Chulalongkorn University, Institute of Health Research
DOCUMENT TYPE: Journal
LANGUAGE: English
AB One-step **ELISA** assay using monoclonal antibody for screening of Hepatitis B surface antigen (HBsAg) was developed in our laboratory and compared with com. **ELISA** test kit. Monoclonal antibody raised against the common "a" determinant of HBsAg was established by fusion of myeloma cell line (P3-X63-Ag 8.653) with spleen cells of BALB/c mice immunized with plasma derived hepatitis B virus vaccine (adr subtype) and used as probe to develop the one-step **ELISA** assay. Four hundred forty seven human sera (245 HBsAg-pos. and 202 HBsAg-neg.), previously tested for the presence of HBsAg by **Abbott diagnostics** **ELISA** test kit, were used as the comparison samples between our one step **ELISA** and com. **ELISA** test kit (Sanofi Pasteur). The results showed that 233 samples were pos. by one-step **ELISA** and 245 samples were pos. by com. **ELISA** kit. The sensitivity specificity and accuracy of our test were 95.1%, 100% and 97.3%, resp. While the pos. and neg. predictive values were 100% and 94.4%, resp. Since the principle of our assay is based on monoclonal antibodies in a one-step assay, it gives advantages of time utilizing and simplicity over assays using heterologous antisera. This principle would also be applicable to a variety of antigen assay for which appropriate monoclonal antibodies are available.
REFERENCE COUNT: 10 THERE ARE 10 CITED REFERENCES AVAILABLE FOR THIS RECORD. ALL CITATIONS AVAILABLE IN THE RE FORMAT

=> third (w) generation
139808 THIRD
6661 THIRDS
145119 THIRD

(THIRD OR THIRDS)

337620 GENERATION

19657 GENERATIONS

352098 GENERATION

(GENERATION OR GENERATIONS)

L17 4196 THIRD (W) GENERATION

=> L17 and L9

L18 0 L17 AND L9

=> abbott and L17

1887 ABBOTT

2 ABBOTTS

1888 ABBOTT

(ABBOTT OR ABBOTTS)

L19 16 ABBOTT AND L17

=> ELISA and L19

57755 ELISA

2201 ELISAS

58681 ELISA

(ELISA OR ELISAS)

L20 4 ELISA AND L19

=> D L20 IBIB ABS 1-4

L20 ANSWER 1 OF 4 CAPLUS COPYRIGHT 2005 ACS on STN

ACCESSION NUMBER: 2004:121427 CAPLUS

DOCUMENT NUMBER: 140:319695

TITLE: Multicenter evaluation of a new, automated enzyme-linked immunoassay for detection of human immunodeficiency virus-specific antibodies and antigen
Sickinger, Eva; Stieler, Myriam; Kaufman, Boris; Kapprell, Hans-Peter; West, Daniel; Sandridge, Arnold; Devare, Sushil; Schochetman, Gerald; Hunt, J. C.; Daghfal, David

CORPORATE SOURCE: AxSYM Clinical Study Group, Abbott Diagnostika GmbH and Co. KG, Wiesbaden, Germany

SOURCE: Journal of Clinical Microbiology (2004), 42(1), 21-29
CODEN: JCMIDW; ISSN: 0095-1137

PUBLISHER: American Society for Microbiology

DOCUMENT TYPE: Journal

LANGUAGE: English

AB A collaborative multicenter study was conducted to evaluate the sensitivity, specificity, and precision of a three-step, fully automated, qual. microparticle-based enzyme-linked immunoassay (AxSYM HIV Ag/Ab Combo; Abbott Labs.), designed to simultaneously detect (i) antibodies against human immunodeficiency virus type 1 (HIV-1) and/or type 2 (HIV-2) and (ii) HIV p24 antigen. A significant reduction in the HIV seroconversion window was achieved by combining detection of HIV antibodies and antigen into a single assay format. For 22 selected, com. HIV seroconversion panels, the mean time of detection with the combined-format HIV antigen-antibody assay was reduced by 6.15 days compared to that with a similar **third-generation** single-format HIV antibody assay. The quant. sensitivity of the combination assay for the p24 antigen (17.5 pg/mL by use of the p24 quant. panel VIH SFTS96') was nearly equivalent to that of single-format antigen tests. The combination assay demonstrated sensitive (100%) detection of anti-HIV Ig in specimens from individuals in CDC stages A, B, and C and from individuals infected with different HIV-1 group M subtypes, group O, or HIV-2. The apparent specificity for hospitalized patients (n = 1,938) was 99.90%. In a random population of 7,900 volunteer blood donors, the specificity (99.87%) was comparable to that of a **third-generation** single-format HIV antibody assay (99.92%) on the same donor specimens. In addition, the combination assay was robust to potential interfering specimens. The precision of the combination was high, with intra- and interrun variances of ≤9.3% for each precision panel specimen or assay control and ≤5.3% for the neg. assay control.

REFERENCE COUNT: 33 THERE ARE 33 CITED REFERENCES AVAILABLE FOR THIS

L20 ANSWER 2 OF 4 CAPLUS COPYRIGHT 2005 ACS on STN
 ACCESSION NUMBER: 2001:287418 CAPLUS
 DOCUMENT NUMBER: 136:64757
 TITLE: Routine HCV PCR screening of blood donations to identify early HCV infection in blood donors lacking antibodies to HCV
 AUTHOR(S): Hitzler, Walter E.; Runkel, Stefan
 CORPORATE SOURCE: Transfusion Center, Johannes Gutenberg Clinic, University of Mainz, Mainz, D-55131, Germany
 SOURCE: Transfusion (Bethesda, MD, United States) (2001), 41(3), 333-337
 CODEN: TRANAT; ISSN: 0041-1132
 PUBLISHER: American Association of Blood Banks
 DOCUMENT TYPE: Journal
 LANGUAGE: English

AB Detection of early hepatitis C infection of blood donors is still a major problem for blood transfusion. Common anti-HCV screening assays show differences in sensitivity and specificity. The often mild symptoms of acute hepatitis C also cause difficulties in the identification of early HCV infection. The feasibility and efficacy of routine screening of blood donations for HCV RNA were investigated. Blood donations (n = 251,737) were screened for HCV RNA over 4 yr. RNA extraction, amplification, and detection were done by two com. HCV PCR kits (HCV Cobas Amplicor and HCV Cobas Amplicor 2.0, Roche Diagnostics). Screening was done by pool testing with a maximum pool size of 40 serum samples. Three donations out 251,737 were HCV RNA pos. and anti-HCV neg. ALT levels of these donations were 271, 32, and 10 U per L. The HCV infection of a fourth HCV RNA-pos. donor could not be identified by routine, second-generation HCV EIA (**Abbott Diagnostika**). In this case, two previous donations were also HCV RNA pos., and three second-generation test systems (**Abbott**) could not detect anti-HCV, whereas **third-generation** anti-HCV screening assays detected antibody with different sensitivity. The first HCV RNA-pos. donation was identified only by the HCV **ELISA 3.0** (Ortho Diagnostic Systems). The results of confirmatory assays like RIBA HCV 3.0 (Ortho) and Matrix (**Abbott**) indicate a restricted immune response to NS3 only. HCV RNA detection by PCR can be carried out routinely in blood donor screening without significant delay of release of the components. The residual risk of transmission can be reduced by identification of early infection, which can lead to an improved of blood components. RNA screening can also be advantageous in cases of incomplete or lack of antibody response to HCV.

REFERENCE COUNT: 15 THERE ARE 15 CITED REFERENCES AVAILABLE FOR THIS RECORD. ALL CITATIONS AVAILABLE IN THE RE FORMAT

L20 ANSWER 3 OF 4 CAPLUS COPYRIGHT 2005 ACS on STN
 ACCESSION NUMBER: 1996:613973 CAPLUS
 DOCUMENT NUMBER: 125:245042
 TITLE: Evaluation of a new automated **third-generation** anti-HCV enzyme immunoassay
 AUTHOR(S): Lavanchy, D.; Steinmann, J.; Moritz, A.; Frei, P. C.
 CORPORATE SOURCE: Centre Hospitalier, Universitaire Vaudois, Lausanne, CH-1011, Switz.
 SOURCE: Journal of Clinical Laboratory Analysis (1996), 10(5), 269-276
 CODEN: JCANEM; ISSN: 0887-8013
 PUBLISHER: Wiley-Liss
 DOCUMENT TYPE: Journal
 LANGUAGE: English

AB The new Cobas Core Anti-HCV EIA was evaluated in two centers for its ability to detect antibodies directed to hepatitis C virus in human serum. This assay, which can be run fully automated on a random access analyzer, was compared with three other com. available screening tests: the Ortho HCV 3.0 **ELISA**, the Murex anti-HCV, and the **Abbott** HCV EIA second generation. Pos. or discrepant results were further investigated using the Wellcozyme HCV Western Blot or the **Abbott** Matrix HCV assays. The results obtained from analyzing 5045 serum samples showed a high correlation between the Cobas Core Anti-HCV EIA and the

other screening assays, ranging from 98.9% to 99.9%. Diagnostic specificities and sensitivities ranged from 99.7% to 100% and from 98.8% to 100%, resp. In this study, the Cobas Core Anti-HCV EIA proved to be a very convenient test, able to perform at the highest levels of sensitivity and specificity.

L20 ANSWER 4 OF 4 CAPLUS COPYRIGHT 2005 ACS on STN

ACCESSION NUMBER: 1995:791425 CAPLUS

DOCUMENT NUMBER: 123:196149

TITLE: Evaluation of the reliability of 6 current anti-HIV-1/HIV-2 enzyme immunoassays

AUTHOR(S): Weber, Bernard; Moshtaghi-Borönjeni, Mahin; Brunner, Michael; Preiser, Wolfgang; Breiner, Markus; Doerr, Hans Wilhelm

CORPORATE SOURCE: Institut fuer Medizinische Virologie, Zentrum der Hygiene, Universitaetskliniken, Paul Ehrlich Strasse 40, Frankfurt/M., 60596, Germany

SOURCE: Journal of Virological Methods (1995), 55(1), 97-104
CODEN: JVMEDH; ISSN: 0166-0934

PUBLISHER: Elsevier

DOCUMENT TYPE: Journal

LANGUAGE: English

AB The sensitivity for early detection of HIV antibodies and specificity of 6 anti-HIV-1/HIV-2 screening enzyme immunoassays (**ELISAs**) currently on the market were investigated by testing a panel of 249 well-characterized serum samples. The panel included sera from AIDS patients or children with congenital HIV infection, high-risk individuals, and patients with conditions unrelated to AIDS. Tricky sera (repeatedly pos. results by **ELISA** and neg. or indeterminate results by Western blot) were also used in this evaluation along with 6 seroconversion panels. One second-generation assay (Biostest) and 2 **third-generation** assays (**Abbott** and **Murex**) showed the highest sensitivity for early detection of HIV-1 antibodies in seroconversion panels. A high specificity was achieved with the Cambridge Biotech (100%) and Ortho **ELISA** (99.4%). A relatively high rate of false-pos. results was obtained with the Biostest and the Pasteur assays by testing tricky sera and samples from high-risk individuals and from patients with other acute viral infections. Thus, it remains difficult to combine high specificity with an accurate detection of early seroconversion for anti-HIV-1/HIV-2 screening enzyme immunoassays.

=> "hcv 3.0 elisa"
· · 9298 "HCV"
· · 17 "HCVS"
· 9302 "HCV"
· · ("HCV" OR "HCVS")
6323708 "3"
5156476 "0"
· 57755 "ELISA"
· 2201 "ELISAS"
· 58681 "ELISA"
· · ("ELISA" OR "ELISAS")
L21 4 "HCV 3.0 ELISA"
· · ("HCV" (W) "3" (W) "0" (W) "ELISA")

=> D L21 IBIB ABS 1-4

L21 ANSWER 1 OF 4 CAPLUS COPYRIGHT 2005 ACS on STN
ACCESSION NUMBER: 2001:904964 CAPLUS
DOCUMENT NUMBER: 136:368034
TITLE: Recognition of multiple classes of hepatitis C
antibodies increases detection sensitivity in oral
fluid
AUTHOR(S): Zmuda, Jonathan F.; Wagoneer, Barbara; Liotta, Lance;
Whiteley, Gordon
CORPORATE SOURCE: Immunomatrix Inc., Gaithersburg, MD, 20878, USA
SOURCE: Clinical and Diagnostic Laboratory Immunology (2001),
8(6), 1267-1270
CODEN: CDIMEN; ISSN: 1071-412X
PUBLISHER: American Society for Microbiology
DOCUMENT TYPE: Journal
LANGUAGE: English
AB Paired serum-oral fluid samples from 127 hepatitis C virus (HCV)-pos. and
31 HCV-neg. patients were tested for the presence of anti-HCV using the
Ortho HCV 3.0 ELISA. Using the
IgG-specific detection antibody provided with the HCV 3
.0 ELISA we attained 100% sensitivity and specificity
with serum samples; however, sensitivity in oral fluid samples was only
81%. By modifying the HCV 3.0 ELISA
to utilize a secondary antibody cocktail that recognizes not only IgG but
IgA and IgM as well, we attained 100% specificity and sensitivity with
oral fluid samples.
REFERENCE COUNT: 18 THERE ARE 18 CITED REFERENCES AVAILABLE FOR THIS
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L21 ANSWER 2 OF 4 CAPLUS COPYRIGHT 2005 ACS on STN
ACCESSION NUMBER: 2001:300382 CAPLUS
DOCUMENT NUMBER: 135:342849
TITLE: Evaluation of hepatitis C antibody testing in saliva
specimens collected by two different systems in
comparison with HCV antibody and HCV RNA in serum
AUTHOR(S): Van Doornum, G. J. J.; Lodder, A.; Buimer, M.; Van
Ameijden, E. J. C.; Bruisten, S.
CORPORATE SOURCE: Division of Public Health, Municipal Health Service of
Amsterdam, Amsterdam, 3015 GD, Neth.
SOURCE: Journal of Medical Virology (2001), 64(1), 13-20
CODEN: JMVIDB; ISSN: 0146-6615
PUBLISHER: Wiley-Liss, Inc.
DOCUMENT TYPE: Journal
LANGUAGE: English
AB Two different ELISA assays, the Ortho HCV 3.0
ELISA (Ortho Diagnostics Systems) and the Mono-Lisa anti-HCV Plus
(Sanofi Diagnostics Pasteur) were evaluated for the detection of hepatitis
C virus (HCV) antibody in saliva samples. Specimens were collected from
152 individuals who participated in a longitudinal cohort study on HIV
infection, and who used illicit drugs. Saliva specimens were collected
using two different systems: Salivette (Sarstedt) and Omni-Sal (Saliva
Diagnostic Systems). Saliva specimens were tested following modified
protocols by both ELISAs, and the results were compared with serum
specimens that were tested according to the instructions of the

manufacturer. Serum samples of 102 (67%) participants were pos. by both assays, and 50 persons were neg. for HCV antibody. A total of 99 of the 102 serum specimens were confirmed as pos. using Ortho Riba HCV 3.0 (Ortho Diagnostics System) and Deciscan HCV (Sanofi Diagnostics Pasteur), and 3 yielded discrepant results. As no cut-off level is known for testing saliva samples by ELISA, 3 different levels were chosen: mean (M) + 1 standard deviation (SD), M + 2 SD, and M + 3 SD of the optical densities of saliva tests of the 50 HCV serum antibody neg. persons. At a level of M + 1 SD and M + 2 SD the Salivette/Mono-Lisa combination gave the greatest proportion of HCV antibody pos. saliva specimens obtained from the 102 HCV serum antibody pos. participants, 88% and 79%, resp. Differences between the various collection systems and assay combinations were not significant statistically. In 76 of the 102 persons with HCV antibodies in serum, HCV RNA was detected in serum. Salivary presence of HCV RNA, however, could not be demonstrated. The results show that the assays compared are unsuitable for diagnostic use, but the sensitivities of the assays are acceptable for use in epidemiol. studies.

REFERENCE COUNT: 23 THERE ARE 23 CITED REFERENCES AVAILABLE FOR THIS RECORD. ALL CITATIONS AVAILABLE IN THE RE FORMAT

L21 ANSWER 3 OF 4 CAPLUS COPYRIGHT 2005 ACS on STN

ACCESSION NUMBER: 1996:737511 CAPLUS

DOCUMENT NUMBER: 126:58542

TITLE: Analytical and laboratory evaluation of a new fully-automated third generation enzyme immunoassay for the detection of antibodies to the hepatitis C virus

AUTHOR(S): Bonanni, P.; Icardi, G. C.; Raffo, A. M.; Ferrari Bravo, M.; Roccatagliata, A.; Crovari, P.

CORPORATE SOURCE: Public Health and Epidemiology Department, University of Florence, Viale G.B. Morgagni 48, Florence, 50134, Italy

SOURCE: Journal of Virological Methods (1996), 62(2), 113-122
CODEN: JVMDH; ISSN: 0166-0934

PUBLISHER: Elsevier.

DOCUMENT TYPE: Journal

LANGUAGE: English

AB An anal. and laboratory evaluation of a newly-developed fully-automated third generation ELISA for the detection of anti-HCV (Cobas Core Anti-HCV EIA, Roche) was undertaken. Coeffs. of variation (CVs) calculated on pos. control and serum samples ranged from 5.9 to 9.8% in the intra-assay precision test and from 3.9 to 11.3% in the inter-assay evaluation. With regard to the study of clin. laboratory performance, five groups of sera pre-screened with two third generation ELISA (Ortho HCV 3.0

ELISA; Innogenetics HCV Ab III) were assayed: anti-HCV neg. samples (n = 932); anti-HCV pos. samples (n = 449); difficult sera of different origin (n = 113); sera with discrepant results in the two ELISAs (n = 50); sera with an indeterminate result in one or more confirmatory test (n = 34). The overall concordance between the Roche anti-HCV EIA and the two reference assays was 97.5 and 97.8% for the Ortho and for the Innogenetics assays, resp. Although it is not possible to provide absolute figures for clin. sensitivity and specificity, the results of the study on discrepant samples show that the Cobas Core Anti-HCV gives a number of neg. results with pos. or indeterminate confirmatory anti-HCV tests, which is intermediate between the Ortho and the Innogenetics assay. In contrast, only 5% Cobas Core Anti-HCV reactive sera are not pos. or clear-cut single band reactive by supplemental assays. The results show that the new fully-automated third generation anti-HCV test is a valid alternative to other com. available assays for screening of antibodies to the hepatitis C virus.

REFERENCE COUNT: 14 THERE ARE 14 CITED REFERENCES AVAILABLE FOR THIS RECORD. ALL CITATIONS AVAILABLE IN THE RE FORMAT

L21 ANSWER 4 OF 4 CAPLUS COPYRIGHT 2005 ACS on STN

ACCESSION NUMBER: 1996:613973 CAPLUS

DOCUMENT NUMBER: 125:245042

TITLE: Evaluation of a new automated third-generation anti-HCV enzyme immunoassay

AUTHOR(S): Lavanchy, D.; Steinmann, J.; Moritz, A.; Frei, P. C.
CORPORATE SOURCE: Centre Hospitalier, Universitaire Vaudois, Lausanne,

CH-1011, Switz.

SOURCE: Journal of Clinical Laboratory Analysis (1996), 10(5),

269-276

CODEN: JCANEM; ISSN: 0887-8013

PUBLISHER:

Wiley-Liss

DOCUMENT TYPE:

Journal

LANGUAGE:

English

AB The new Cobas Core Anti-HCV EIA was evaluated in two centers for its ability to detect antibodies directed to hepatitis C virus in human serum. This assay, which can be run fully automated on a random access analyzer, was compared with three other com. available screening tests: the Ortho HCV 3.0 ELISA, the Murex anti-HCV, and the Abbott HCV EIA second generation. Pos. or discrepant results were further investigated using the Wellcozyme HCV Western Blot or the Abbott Matrix HCV assays. The results obtained from analyzing 5045 serum samples showed a high correlation between the Cobas Core Anti-HCV EIA and the other screening assays, ranging from 98.9% to 99.9%. Diagnostic specificities and sensitivities ranged from 99.7% to 100% and from 98.8% to 100%, resp. In this study, the Cobas Core Anti-HCV EIA proved to be a very convenient test, able to perform at the highest levels of sensitivity and specificity.

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1: [Antipa C, Ruta S, Cernescu C.](#)

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Serological profile assessment of the infection with hepatitis C virus (HCV) in haemophiliacs and thalassemic patients.
Rom J Virol. 1996 Jan-Dec;47(1-4):3-11.
PMID: 9495779 [PubMed - indexed for MEDLINE]

2: [Maillard MF, Poinard T, Dubreuil P, Agostini H, Hautecoeur B, Pillot J, Chaput JC.](#)

Related Articles, Links

[Prevalence of serum anti-hepatitis C virus antibodies and risk factors of contamination in the personnel of a hospital in the Paris region. A prospective survey]
Gastroenterol Clin Biol. 1996;20(12):1053-7. French.
PMID: 9033850 [PubMed - indexed for MEDLINE]

3: [Hennig H, Haase D, Kirchner H.](#)

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[Prevalence of hepatitis C virus in blood donors and comparison of 4 different anti-HCV differentiation tests]
Beitr Infusionsther Transfusionsmed. 1996;33:231-4. German.
PMID: 8974699 [PubMed - indexed for MEDLINE]

4: [Lavanchy D, Steinmann J, Moritz A, Frei PC.](#)

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Evaluation of a new automated third-generation anti-HCV enzyme immunoassay.
J Clin Lab Anal. 1996;10(5):269-76.
PMID: 8887006 [PubMed - indexed for MEDLINE]

5: [Martins RM, Porto SO, Vanderborght BO, Rouzere CD, Queiroz DA, Cardoso DD, Yoshida CF.](#)

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Short report: prevalence of hepatitis C viral antibody among Brazilian children, adolescents, and street youths.
Am J Trop Med Hyg. 1995 Dec;53(6):654-5.
PMID: 8561271 [PubMed - indexed for MEDLINE]

6: [Vrielink H, Zaaijer HL, Reesink HW, Lelie PN, van der Poel CL.](#)

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Comparison of two anti-hepatitis C virus enzyme-linked immunosorbent assays.
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PMID: 7631395 [PubMed - indexed for MEDLINE]

7: [Carella C, Amato G, Biondi B, Rotondi M, Morisco F, Tuccillo C, Chiuchiolo N, Signoriello G, Caporaso N, Lombardi G.](#)

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Longitudinal study of antibodies against thyroid in patients undergoing interferon-alpha therapy for HCV chronic hepatitis.
Horm Res. 1995;44(3):110-4.
PMID: 7590640 [PubMed - indexed for MEDLINE]

□ 8: [Courouce AM, Bouchardieu F, Chauveau P, Le Marrec N, Girault A, Zins B, Naret C, Poignet JL](#) [Related Articles](#), [Links](#)

□ Hepatitis C virus (HCV) infection in haemodialysed patients: HCV-RNA and anti-HCV antibodies (third-generation assays).
Nephrol Dial Transplant. 1995;10(2):234-9.
PMID: 7538650 [PubMed - indexed for MEDLINE]

□ 9: [Barrera JM, Francis B, Ercilla G, Nelles M, Achord D, Darner J, Lee SR](#) [Related Articles](#), [Links](#)

□ Improved detection of anti-HCV in post-transfusion hepatitis by a third-generation ELISA.
Vox Sang. 1995;68(1):15-8.
PMID: 7536987 [PubMed - indexed for MEDLINE]

□ 10: [Zhang ZQ, Zhou GY, Huang TR](#) [Related Articles](#), [Links](#)

□ [A case-control study on relationship between hepatitis C infection and primary liver cancer]
Zhonghua Zhong Liu Za Zhi. 1994 Sep;16(5):327-30. Chinese.
PMID: 7534684 [PubMed - indexed for MEDLINE]

□ 11: [Tobler LH, Busch MP, Wilber J, Dinello R, Quan S, Polito A, Kochesky R, Bahl C, Nelles M, Lee SR](#) [Related Articles](#), [Links](#)

□ Evaluation of indeterminate c22-3 reactivity in volunteer blood donors.
Transfusion. 1994 Feb;34(2):130-4.
PMID: 8310482 [PubMed - indexed for MEDLINE]

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#33	Search C22 and HCV diagnosis and ELISA and 3.0 Field: All Fields, Limits: Publication Date to 1996/05/27	14:09:49	1
#32	Search C22 and HCV diagnosis and ELISA Field: All Fields, Limits: Publication Date to 1996/05/27	14:09:34	41
#31	Search C22 and HCV diagnosis Field: All Fields, Limits: Publication Date to 1996/05/27	14:09:24	73
#29	Search 3rd generation of HCV ELISA Field: All Fields, Limits: Publication Date to 1996/05/27	13:31:34	12
#27	Search ELISA 3 and HCV and microplate Field: All Fields, Limits: Publication Date to 1996/05/27	13:27:24	0
#24	Search ELISA 3 and HCV and 96 well Field: All Fields, Limits: Publication Date to 1996/05/27	13:26:28	5
#23	Search ELISA 3 and HCV Field: All Fields, Limits: Publication Date to 1996/05/27	13:26:17	481
#18	Search ELISA-3 and HCV diagnostic Field: All Fields, Limits: Publication Date to 1996/05/27	13:19:44	6
#12	Search RIBA-3 and HCV and NS5 Field: All Fields, Limits: Publication Date to 1996/05/27	13:12:21	7
#11	Search RIBA-3 and HCV Field: All Fields, Limits: Publication Date to 1996/05/27	13:12:14	32
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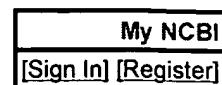
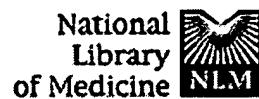
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1: Transfusion. 1995 Jul;35(7):601-4.

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Comparison of two anti-hepatitis C virus enzyme-linked immunosorbent assays.

Vrielink H, Zaaijer HL, Reesink HW, Lelie PN, van der Poel CL.

Red Cross Blood Bank Amsterdam, The Netherlands.

BACKGROUND: Third-generation anti-hepatitis C virus (HCV) enzyme-linked immunosorbent assays (ELISA) are now implemented in most laboratories in Europe, but have not yet been fully implemented in the United States. **STUDY DESIGN AND METHODS:** Two ELISAs (Ortho 3.0 and Ortho 2.0, Ortho Diagnostics, Raritan, NJ) were compared by tests on various serum panels: A) blood donor samples ($n = 530$) that tested positive in first- or second-generation anti-HCV ELISA; B) samples from persons with chronic non-A, non-B hepatitis ($n = 185$); C) samples from multiply transfused patients ($n = 79$); D) samples from patients on hemodialysis ($n = 473$); and E) samples from Dutch random blood donors ($n = 2153$). **RESULTS:** In panels A, B, and C, 247 (100%) of 247 polymerase chain reaction (PCR)-positive and 278 (100%) of 278 second-generation recombinant immunoblot assay (RIBA-2)-positive specimens were detected by Ortho 2.0 and 3.0 (sensitivity, 100%). In the sera of panel D, used to represent a group of patients with a high risk for HCV, no additional positives were found by Ortho 3.0. In panel E, of 2153 blood donor samples, 2 (0.1%) were positive in Ortho 2.0 and 8 (0.4%) in Ortho 3.0. Two samples that were positive in both Ortho 2.0 and 3.0 were also positive in RIBA-2; one was positive on PCR. From the 6 remaining Ortho 3.0-positive (Ortho 2.0-negative) samples, 1 was positive in RIBA-2 (isolated anti-c100) and 3 were positive in third-generation RIBA (1/3 isolated anti-c100, 2/3 isolated NS5). All 6 samples were PCR negative. In first-time donors, no difference in specificity was found. **CONCLUSION:** The sensitivity and specificity of the Ortho 3.0 ELISA are comparable to those of the Ortho 2.0 ELISA.

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1: Transfusion. 1994 Jul;34(7):603-7.

Related Articles, Links

Confirmation of hepatitis C infection: a comparison of five immunoblot assays.

Zaaijer HL, Vrielink H, van Exel-Oehlers PJ, Cuypers HT, Lelie PN.

Viral Serology Department, Central Laboratory of the Netherlands Red Cross Blood Transfusion Service, Amsterdam.

BACKGROUND: Recently, new immunoblot assays for the detection of antibodies to hepatitis C virus (HCV) became available. **STUDY DESIGN AND METHODS:** The performance of five confirmatory anti-HCV immunoblot assays was studied with samples with known HCV antibody and HCV RNA status. The assays were a third-generation strip recombinant immunoblot assay (RIBA-3, Chiron Corp., Emeryville, CA), a second-generation HCV blot (DB-2 blot, Diagnostic Biotechnology, Singapore), the Wellcozyme HCV Western blot (Murex blot, Murex Diagnostics, Dartford, UK), an immunodot HCV assay (Matrix, Abbott Laboratories, Chicago, IL), and the third-generation HCV line immunoassay (Liatek-III, Organon Teknika, Boxtel, The Netherlands). **RESULTS:** Sensitivity on samples from 48 HCV RNA-positive, second-generation RIBA (RIBA-2)-positive persons and specificity on samples from 31 low-risk donors was 96 percent or better for all assays. The sensitivity on 31 HCV RNA-positive, RIBA-2-indeterminate samples was as follows: Liatek-III, 94 percent; RIBA-3, 90 percent; Murex blot, 61 percent; Matrix, 55 percent; and DB-2 blot, 39 percent. In testing 39 HCV RNA-negative, RIBA-2-indeterminate donor samples, the percentage found to be negative was Liatek-III, 77 percent; RIBA-3, 67 percent; Murex blot, 49 percent; DB-2 blot, 33 percent; and Matrix, 15 percent. The order of sensitivity on four HCV seroconversion series was (from high to low): RIBA-3, Liatek-III, DB-2 blot, Murex blot, and Matrix; the differences were small. **CONCLUSION:** Detection of HCV antibodies was not refined by the addition of new HCV antigens (NS5, E2/NS1), but by improved classical antigens (core, NS3, NS4). Replacement of the commonly used RIBA-2 will resolve the status of a high proportion of RIBA-2-indeterminate samples.

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1: Hepatology. 1995 Mar;21(3):730-4.

Related Articles, Links

Hepatocellular codistribution of c100, c33, c22, and NS5 hepatitis C virus antigens detected by using immunopurified polyclonal spontaneous human antibodies.

Ballardini G, Groff P, Giostra F, Francesconi R, Miniero R, Ghetti S, Zauli D, Bianchi FB.

Cattedra di Medicina Interna II, University of Bologna, Italy.

Hepatitis C virus (HCV) antigens in liver biopsy have been detected by immunohistochemistry using both spontaneous human IgG and murine monoclonal or rabbit polyclonal monospecific reagents. Conflicting results have been obtained in different studies. This was probably because of the incapacity of single experimental antibodies, raised against synthetic or recombinant peptides, to recognize native tissue antigens. To overcome this possibility, we immunopurified monospecific spontaneous polyclonal human Ig, therefore induced by native antigens, from the single antigen-containing bands of RIBA 3 strips. Antibodies to c100, c33, c22, and NS5 antigens were obtained from the serum of a patient affected by chronic hepatitis C. The IgG fraction of this serum had proved to stain tissue HCV antigens. Eight biopsies were selected on the basis of strong hepatocellular reactivity with the whole IgG fraction in a variable number (from 5% to 75%) of cells. The four antigens were detected in all biopsies; a clear cellular codistribution was observed on serial sections. These data demonstrate that the possibility to identify HCV antigens in liver biopsies is higher when using human antibodies induced by native antigens rather than experimental antibodies. The approach of immunopurification of human antibodies can be extended to other HCV-related epitopes to obtain reagents useful for the selection and optimization of monoclonal or polyclonal antibodies.

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1: New Microbiol. 1993 Jan;16(1):35-42.

Related Articles, Links

Specificity and sensitivity of 3rd generation EIA for detection of HCV antibodies among intravenous drug-users.

Filice G, Patruno S, Campisi D, Chiesa A, Orsolini P, Debiaggi M, Bruno R, Tinelli M.

Institute of Infectious Diseases, University of Pavia, Italy.

Serum samples from 487 ambulatory I.V. drug users were screened for HIV and HCV antibodies to determine the prevalence of coinfection in this high risk group for AIDS. For anti-HCV antibody screening we first used a 3rd generation EIA using, as antigen synthetic peptides which were not subjected to false positive results due to antibodies against superoxide dismutase or against yeast proteins (which may copurify with the recombinant proteins employed in the first and second generation test). The specimens that were positive in the screening test were confirmed by a more specific EIA system that detect antibodies to proteins encoded by structural (HCV-st EIA) and non structural (HCV-nst-EIA) regions of the HCV genome. A second confirmation assay was also performed: sera were run in presence or absence of blocking reagents which inhibits antibodies to C200 and C22 HCV epitopes for binding to the solid phase. The sensitivity of the HCV EIA screening for human HCV antibody detection revealed a 100% positivity for HCV infection. The confirmatory strategy presented in this paper revealed an HCV EIA specificity of 98.6%. In this work we demonstrated a significantly higher prevalence ($p < 0.001$) of HCV exposure in HIV infected individuals compared to the general population. Our experimental data also confirmed that HBV infection in drug-users at high risk for HIV infection was significantly associated with HCV infection ($p < 0.001$). In contrast, the acquisition of HIV by sexual contact was not a statistically significant risk factor for HCV coinfection.

PMID: 7682283 [PubMed - indexed for MEDLINE]

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1: Vox Sang. 1994;66(2):122-9.

Related Articles, Links

Evaluation of third-generation screening and confirmatory assays for HCV antibodies.

Uyttendaele S, Claeys H, Mertens W, Verhaert H, Vermeylen C.

Belgian Red Cross Blood Transfusion Center, Leuven.

A third-generation (gen.) screening and immunoblot assay (Ortho EIA-3.0; Chiron RIBA-3 prototype), using antigens derived from the capsid and different nonstructural regions (NS3, NS4 and NS5) of the hepatitis C virus viral genome, were evaluated in comparison with the corresponding second-gen. assays (Ortho EIA-2.0; revised Ortho EIA-2.5; Chiron RIBA-2). In 203 depository sera of blood donors, positive in EIA-2.0, specificity of the screening assays was improved as shown by an increase in positive predictive value for viral carrier state from 0.23 (EIA-2.0) to 0.37 (EIA-2.5) and 0.52 (EIA-3.0). Comparing the confirmation patterns on RIBA-2 and RIBA-3, this amelioration was mainly due to the specific elimination of false-positive c22-3 and c100-3 reactions. Antibody response to the newly added NS5 antigen was not as prevalent as to the other antigens and had only a minor influence in sample allocation. In contrast, screening of 1,560 volunteer blood donors and 47 hemodialysis patients revealed 3 additional positive sera, only reacting with the NS5 antigen. However none of these isolated NS5 reactions could be confirmed on synthetic peptides [INNO-LIA: NS5(p)] and none was PCR positive. A documented seroconversion, detected earlier with EIA-3.0, was related to a better immunological response to the NS3 antigen and not to the additional NS5. From this pilot study third-gen. assays appeared extremely useful in the reevaluation of HCV-seropositive depository sera. However the additional value of the NS5 antigen in blood donor screening is still hypothetical and remains to be established in larger screening studies.

PMID: 7514324 [PubMed - indexed for MEDLINE]

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1: J Virol Methods. 1996 May;59(1-2):141-6.

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Lack of correlation between different hepatitis C virus screening and confirmatory assays.

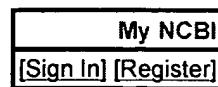
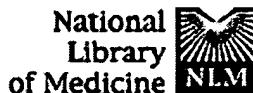
Berger A, Doerr HW, Preiser W, Weber B.

Institut fur Medizinische Virologie, Zentrum der Hygiene Universitatskliniken Frankfurt a. M., Germany.

Numerous 2nd and 3rd generation screening and confirmatory assays for the detection of anti-HCV antibodies have been introduced on the international market. The aim of the present study was to compare the performance of five different commercially available screening assays and four 'confirmatory' assays in a panel of serum samples that had tested positive or borderline with a 2nd generation EIA (Abbott HCV EIA 2nd generation). Considerable discrepancies were observed between the different screening assays and confirmatory tests. The antigens from the putative 'core' region of HCV were recognized most frequently by the confirmatory assays. By considering the reactivity to either NS5 (RIBA III and Inno-LIA) or E2/NS1 antigens (Inno-LIA Ab III) no sample could be identified as anti-HCV positive that would otherwise have been regarded as borderline or negative according to its banding pattern with core, NS3 and NS4 proteins. All 24 HCV-RT-PCR positive samples were anti-HCV reactive by the screening EIAs but only 18 and 21 samples were confirmed anti-HCV positive with the RIBA II and III, respectively. A clear association was observed between HCV-RNAemia in serum samples and index values (O.D. sample/O.D. cut-off) of the screening EIAs as well as with the number of reactive proteins in the confirmatory assays. In conclusion, the results of current screening and confirmatory assays are highly divergent. The additional diagnostic significance of the relatively expensive and labour-intensive immunoblots appears to be very limited. For the serological diagnosis of HCV infection and for blood donor screening, confirmatory assays should only be used if there is a borderline result by HCV EIA. The determination of infectivity by qualitative PCR and the follow-up of patients undergoing IFN therapy by HCV-RNA quantification appears to be much more useful.

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